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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,221	08/28/2003	Michael W. Wathen	Pharmacia Case 01669	7644

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/651,221	MICHAEL W. WATHEN ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Response to the Restriction Requirement filed September 23, 2004 is acknowledged. Applicants have elected without traverse Group I, drawn to methods of instant Formula VI or VII, for preventing or treating inflammatory response associated with atherosclerosis administering a cinnolinecarboxamide of instant Formula VI or VII, in which no heterocyclic ring system other than morpholine, thiomorpholine, oxazolidine, triazine, imidazole, furan or pyran is present.

Accordingly, those methods of claims 1-21 limited to compounds of instant Formula VI or VII, in which no heterocyclic ring system other than morpholine, thiomorpholine, oxazolidine, triazine, imidazole, furan or pyran is present for preventing or treating inflammatory response associated with atherosclerosis represent the subject matter presently under consideration. Those methods drawn to the administration of other heterocyclic ring systems not encompassed in the group set forth supra are presently withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as directed to non-elected inventions. Further, in response to a request for an election of species, Applicants elected the compound N-(4-chlorobenzyl)-4-hydroxy-6-(tetrahydro-2H-pyran-4-ylmethyl)-3-cinnolinecarboxamide.

Two Information Disclosure Statements filed February 28, 2004 and May 27, 2004 are further acknowledged and have been reviewed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-24 of copending Application No. 10/651290. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In the last Office Action claims 5-16 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. It was asserted the formulas designated as VII, VIII and IX, respectively, in claims 5, 9 and 14 lack clear antecedent basis in claim 1.

The merits of this rejection were discussed in a telephone interview on May 24, 2004. At that time Applicants argued Formula VI and its substituent definitions in dependent claim 2, Formula VII and its substituent definitions in dependent claim 5, Formula VIII and its substituent definitions in dependent claim 9 and Formula IX and its substituent definitions in dependent claim 14 are the same as the corresponding

formulas and substituent definitions in independent claim 1. At that time the Examiner recognized Applicants' position. However, upon further reconsideration and after discussion with a supervisory Examiner, it was concluded the format of claim 1 is improper in that the dependent claims do not further limit the subject matter of independent claim one. It is suggested either four independent claims are presented wherein all limitations of each of Formulas VI, VII, VIII and IX are respectively recited, or, all four formulas are completely defined in claim one. Because the format of the claims lacks clarity, the rejection of record of claims 5-16 is maintained.

Claims 1-21 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims were directed to the treatment or prevention of atherosclerosis or restenosis comprising administering a cinnoline or naphthyridine carboxamide compound of instant formulas VI, VII, VIII or IX. The specification provides a brief discussion of animal models to evaluate reduction of atherosclerosis or restenosis by administration of antiviral drug treatment. The models are directed to murine CMV infection and MHV, a murine gamma-herpes virus related to EBV. Applicants state compounds of the instant invention inhibit replication of viruses and show an effect on the development of atherosclerosis. Two authors are cited to provide support; however, the references are not provided.

Applicants argue the prior art teaches the prevention and retarding of atherosclerotic lesions or restenosis in mammals and the present specification provides

pharmaceutical compositions, means of preparing them and dosage ranges for the claimed compounds.

The Examiner was well aware of the inflammatory component in the development of atherosclerosis or restenosis before reviewing the submitted prior art filed February 28, 2004 and May 27, 2004. No assertion of incredible utility was set forth. However, the instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation.

With respect to the nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art, the statement is based on a reasonable assertion that each particular atherosclerotic or restenotic event has its own specific characteristics and etiology. The broad recitation " treatment or prevention of atherosclerosis or restenosis" is inclusive of many conditions that presently have no established successful therapies.

With respect to the breadth of the claims, the statement is based on a reasonable assertion that a plethora of compounds is herein claimed. The art does not recognize established therapeutic modalities for preventing atherosclerosis or restenosis.

With respect to the amount of direction or guidance provided and the presence or absence of working examples, there are no working examples or guidance provided as to which compounds are preferred and none is required.

As to the quantity of experimentation necessary, the instant specification sets forth no understanding or any criteria for extrapolating beyond an inhibition of the

replication of a virus. The skilled artisan would not readily conclude the inhibition of the replication of a virus, as shown by a particular compound, as for example, the administration of an immunogenic C. *pneumoniae* protein or fragment thereof, taught in U.S. Patent 6,291,437, provides an expectation of success in the prevention or treatment of an inflammatory response associated with atherosclerosis or restenosis following the administration of any compound. No direction is provided to treat restenosis. Absent reasonable *a priori* expectations of success, one skilled in the art would have to test extensively many compounds to discover which particular one shows efficacy for either condition. For these reasons undue experimentation would be required to practice the invention as it is claimed in its current scope.

The rejection of claims 1-21 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention is maintained.

Claims 1-21 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

One skilled in the art would have reasonably been knowledgeable as to the breadth of the plethora of heterocyclic compounds within the definitions of the terms. The examples disclosed in U.S. Patent 6,413,958 provides further support as to the compounds contemplated. This rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn.

The elected species is free of the prior art. The search has been extended according to current Markush practice.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

January 2, 2005